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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	1372.34	2429
21901	7590	07/21/2009		
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677				
EXAMINER				
ANGELL, JON E				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
07/21/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/939,518

Applicant(s)

JAROSZESKI ET AL.

Examiner

J. E. Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 8, 10, 21, 22, 25, 27 and 28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 2, 6, 8, 10, 21, 22, 25, 27, 28 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the communication filed on 4/13/2009.

The amendment filed 4/13/2009 is acknowledged and has been entered.

Claims 1, 2, 6, 8, 10, 21, 22, 25, 27, 28 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 8, 10, 21, 22, 25, 27, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/43702 (Mathiesen).

4. Mathiesen teaches a method for delivering a molecule into a tissue by introducing the molecule into the tissue and applying an electric field to the tissue wherein the electric field is a single continuous electric field in the range of 1V/cm to 200V/cm and applied for a duration of in the range of 200ms to 20 minutes, thereby effecting a change in porosity of the cell of the target tissue in response to the application of the electric field, where the change in porosity is

sufficient to facilitate entry of the molecule into an interior of a cell in the tissue. Specifically, Mathiesen teaches injecting a DNA plasmid containing a beta-galactosidase gene into the muscle of rats and applying a single bipolar pulse of 25V for 5000 μ s (i.e., 500ms), resulting in the transfection of cells of the muscle tissue with the DNA plasmid (e.g., see Examples 5 and 6 on page 13, Figure 15, etc.) Also see claims 1-3, which are drawn to:

1. A method of delivering a molecule to the skeletal muscle of a mammal in vivo comprising:
injecting a molecule into a skeletal muscle of the mammal;
positioning electrodes near the injection site such that current traveling through the electrodes passes through the injection site; and
electrically stimulating the muscle with an electrical current having a field strength in the range of from about 25 V/cm to less than 200 V/cm.
2. The method of delivering a molecule of claim 1 wherein said electrical stimulation is delivered in the form of a single square bipolar pulse.
3. The method of delivering a molecule of claim 2 wherein said bipolar pulse has a duration of between about 50 μ s and 5000 μ s.

It is also noted that Figure 1 clearly shows syringe injection.

Furthermore, it is respectfully pointed out that claim 21 is drawn to a method comprising applying an electric field to the tissue wherein the electric field is a single continuous electric field in the range of 1V/cm to 200V/cm and applied for a duration of in the range of 200ms to 20 minutes. Mathiesen clearly teaches administering 100 bipolar pulses for 2000 μ s (i.e., 200ms) (see Example 5 and Table 3, page 13).

5. Therefore, Mathiesen anticipates the instant claims.

Response to Arguments

6. Applicant's arguments filed 4/13/2009 have been fully considered, but are moot in view of the new ground(s) of rejection which is based on art identified upon updating the search.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635